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ASX RELEASE

Phase III CimetrA™ clinical trial commences with first patient recruited

Key Highlights:

- The first patient has been recruited under local Ethics Committee approval into MGC's Phase III double blind placebo-controlled clinical trial for CimetrA™ at the Rambam Medical Center, Israel
- This follows completion of CimetrA™ IMP production, validation, and ethics committee approval
- Recruitment is ongoing, and a total of 252 patients will be recruited across both the Rambam Health Care Campus and Nazareth Hospital EMMS in Israel
- The trial and its protocols have been designed to evaluate CimetrA™ on hospitalised patients infected with moderate forms of COVID-19
- The Trial will provide additional data for claims on the Product as an IMP, and essential data to plan a future regulatory pathway for CimetrA™ registration
- MGC has the required facilities, permits and approvals to start commercial production of CimetrA™
- CimetrA™ encapsulates Graft Polymer's proprietary GraftBio™ SNEDDS technology (Self-Nano Emulsifying Drug Delivery System), a unique platform to deliver active ingredients more effectively in higher concentrations to the cells, improving the bioavailability and synergy of natural active ingredients

MGC Pharmaceuticals Ltd (ASX, LSE: MXC, 'MGC Pharma' or 'the Company'), a European based bio-pharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to announce that the phase III clinical trial (the "**Trial**") to evaluate the efficacy and safety of CimetrA™ as a treatment for hospitalised patients diagnosed with COVID-19, and to provide additional data for claims on the product as an IMP, has now commenced following the recruitment of the first patient at the Rambam Medical Center in Israel.

This follows the completion of CimetrA™ IMP production and validation (from supplement production) and ethics committee approval which was received in March (refer to release 23 March 2021).

The Trial will enrol a total of 252 patients,28 days per patient, full details on the Phase III clinical trial required for compliance with the ASX Code of Best Practice for Reporting by Life Science Companies are included in Annexure A.

Now the Trial has commenced, MGC Pharma will complete all the required clinical data for meeting the European Medicines Agency's (EMA) qualification and will look to submit additional pre-clinical and dose finding studies to meet all EMA requirements with the phase III study results.

Trial overview and protocols (Annexure A)

The Phase III clinical trial is designed to test CimetrA™ on moderate hospitalised patients infected with COVID-19 for safety and efficacy, with the purpose of treating the pathophysiological repercussions of infection with the novel coronavirus 2019 (SARS-CoV19).

The Trial will assess the efficacy and safety of the natural anti-inflammatory formulation CimetrA™, based on Curcumin and Boswellia Serrata as Anti-inflammatory agents which are all well-known

natural active ingredients with immunomodulatory properties. As part of the Trial, CimetrA™ will also incorporate a new polymeric drug carrier, GraftBio™ (SNEDD – Self Nano Drug Delivery), to deliver natural ingredients more effectively in higher concentrations.

MGC Pharma will own the intellectual property generated from the Trial. The results from the Trial will determine what valid claims can be made in relation to the Product, provide data points for future trials and will be material to the commercial discussions the Company is currently undertaking with respect to potential supply and sale agreements of the Product in the short term.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "The commencement of the Phase III clinical trial is a milestone achievement for both MGC Pharma and the medicinal cannabis industry. Testing CimetrA™ as an IMP will have great implications for those suffering with COVID-19 and ensure the risk of healthcare systems becoming overwhelmed is minimised."

--Ends--

Authorised for release by the Board, for further information please contact:

MGC Pharmaceuticals Ltd
Roby Zomer
CEO & Managing Director
+61 8 6382 3390
info@mgcpharma.com.au

UK PR Advisors – Tavistock
Tim Pearson
+44 207 920 3150
Tim.Pearson@tavistock.co.uk

UK Broker – Turner Pope
Andy Thacker
+44 203 657 0050
info@turnerpope.com

Australian IR Advisors – Media & Capital Partners
Rod Hinchcliffe
+61 412 277 377
Rod.Hinchcliffe@mcpartners.com.au

About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, ASX: MXC) is a European based bio-pharma company developing and supplying affordable standardised phytocannabinoid derived medicines to patients globally. The Company's founders were key figures in the global medical cannabis industry and the core business strategy is to develop and supply high quality phytocannabinoid derived medicines for the growing demand in the medical markets in Europe, North America and Australasia. MGC Pharma has a robust product offering targeting two widespread medical conditions – epilepsy and dementia – and has further products in the development pipeline.

Employing its 'Nature to Medicine' strategy, MGC Pharma has partnered with renowned institutions and academia to optimise cultivation and the development of targeted phytocannabinoid derived medicines products prior to production in the Company's EU-GMP Certified manufacturing facility.

MGC Pharma has a number of research collaborations with world renowned academic institutions, and including recent research highlighting the positive impact of using specific phytocannabinoid formulations developed by MGC Pharma in the treatment of glioblastoma, the most aggressive and so far therapeutically resistant primary brain tumour.

MGC Pharma has a growing patient base in Australia, the UK, Brazil and Ireland and has a global distribution footprint via an extensive network of commercial partners meaning that it is poised to supply the global market.

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ANNEXURE A

Name and any unique identifier of the trial:	A Phase III, double blind, controlled clinical study designed to evaluate the effect of CimetrA™ in patients diagnosed with COVID-19.
Primary endpoint(s):	Time to sustained clinical improvement, defined as a National Early Warning Score 2 (NEWS2) of 2 maintained for 24 Hours in comparison to routine treatment (measured on days 7, 14, 28)
Secondary endpoints:	• Number of participants depending on oxygen supplementation through day 28 since onset of symptoms. • Change in inflammatory marker levels – IL-6, IL-1β, IL-12, TNF α, IFN-γ, CRP, NLR (Neutrophil / Lymphocyte ratio) at days 1, 2, 4, 7, compared to baseline. • Definition of the active dose of CimetrA • Pharmacokinetic profile of the study drug • Incidence and duration of mechanical ventilation • Incidence of Intensive Care Unit (ICU) stay during COVID-19 complication. • Percentage of participants with definite or probable drug related adverse events. • Long term adverse events of COVID-19 on Day 28. • Quality of life of patients on Days 0, 14 and 28. • The exploratory outcomes: - Course of change in D Dimer levels compared to baseline. - Occurrence of secondary infections.
Blinding status:	Double Blinded
Product status:	The Product will be packaged and labelled in compliance with Good Manufacturing Practice (GMP)
Treatment method, route, frequency, dose levels:	<u>Study Product :</u> Arm 1: CimetrA-1, with a total dose containing a combination of Artemisinin 12 mg, Curcumin 40 mg, Boswellia 30 mg and Vitamin C 120 mg in spray administration – divided in 4 separate doses given as an add on therapy, 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). Arm 2: CimetrA-2, with a total dose containing a combination of Artemisinin 8.4 mg, Curcumin 28 mg, Boswellia 21 mg and Vitamin C 84 mg in spray administration – divided in 4 separate doses given as an add on therapy, 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). Arm 3: Placebo, composed of the same solvent but without active ingredients, given as an add on therapy in spray administration, 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). <u>Study Procedures:</u> The study will last for 4 weeks, and any additional time required for follow up until hospital discharge in order to check side effects and study drug efficacy. <u>Methodology</u>: Multi-center multinational-controlled study. 252 adult patients who suffer from moderate COVID-19 infection.

	Safety will be assessed through collection and analysis of adverse events, blood and urine laboratory assessments and vital signs. After Screening visit, the study drug will be administrated twice a day morning and evening (every 12 hours) during (day 1 and day 2). The patients will be randomized in 1:1:1 ratio to study drug (CimetrA) in addition to Standard of Care (Arm 1 (CimetrA-1) or Arm 2 (CimetrA-2)) or to Placebo in addition to Standard of Care (Arm 3).
Number of trial subjects:	Total of 252 adult patients, across Israel and Brazil, who suffer from COVID-19 infection.
Description of Control Group:	Placebo + Standard of Treatment
Subject selection criteria:	**Inclusion Criteria:** • Confirmed SARS-CoV-2 infection • Hospitalized COVID-19 patient in stable moderate condition (i.e., not requiring ICU admission) • Age – 18 and above • NEWS2 Score of 4 or above • Ability to receive treatment by spray into the oral cavity. • Subjects must be under observation or admitted to a controlled facility or hospital (home quarantine is not sufficient) **Exclusion Criteria:** • Tube feeding or parenteral nutrition. • Respiratory decompensation requiring mechanical ventilation • Uncontrolled diabetes Type 2 • Autoimmune disease • Pregnant or lactating women • Any condition which, in the opinion of the Principal Investigator, would prevent full participation in this trial or would interfere with the evaluation of the trial endpoints.
Trial locations:	Multiple Sites in Israel
Name of the principal investigator:	Dr Hamudi, Rambam Medical Center Dr Elemy (Nazareth Hospital EMMS)
Partners:	Galilee-CBR (CRO)
Expected duration:	The Trial is expected to commence in the coming week and conclude around September 2021 with results then available in October 2021
Additional information:	NA
Trial standard:	This Clinical Trial will be conducted in compliance with Good Clinical Practices (GCP)